

## REMARKS

Claims 1, 2, 4, 5 and 7 to 12 are under examination. Claims 1 and 12 have been previously amended. Claims 3 and 6 have been cancelled and added into claim 1 in a prior amendment.

**Application History:** The patent application was filed on 4/29/2003. The first office action was issued on 7/25/2005 rejecting Claims 1 to 14 under 335 U.S.C. 103(a) as being unpatentable over Farley et al in combination with Del Giglio. An amendment was filed on 10/24/2005. An interview was had on 10/13/2005. A second office action was issued on 1/12/2006 which rejected Claims 1 to 5, 7, 8, 12 under 35 U.S.C. 103(a) as being unpatentable over Nichols in combination with Del Giglio and Proebstle et al. {There is no reference to any column and line number or drawing figure}

As to the Del Giglio reference, the Examiner states, “teaches precise placement of an optical fiber, which can be 400 microns in diameter with a bare tip that is extended 1 cm beyond the tip of the introducer, and applying laser pulses.” This statement being in the first office action.

In the second office action the same words are used verbatim.

As to the second reference, it states, “Nichols teaches a method of treating varicoceles by threading a catheter through the venous system and heating material in the vicinity of the end of the device, which can be done by laser radiation.” {no reference to any column and line number or drawing figure of Nichols.}

As to Proebstle et al, “since these structures also can be efficaciously treated by laser application, and in either case to employ a 940 nm diode laser, as taught by Proebstle et al. since this is not critical and produces no unexpected result;” Page 2 of the second office action.

Reference is made to MPEP 706.02(j), see Exhibit 1, wherein it states, “the examiner should set forth in the Office action: (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate, …”

Also noted to establish a *prima facie* case, “First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.”

The Examiner has failed to provide any such support for these rejections except to make broad statements about the references, which has forced the applicant to only surmise the factual

support for the conclusory statements made as the above demonstrates in responding to these statements.

As further noted in MPEP 2144.08, Section III, page 2100-160 to 161, “the findings should clearly articulate {underling added} which portions of the reference support any rejection. Explicit findings on motivation or suggestion to select the claimed invention should also be articulated {underling added} in order to support a 35 U.S.C. 103 ground of rejection. .... Conclusory statements of similarity or motivation, without any articulated rationale or evidentiary support, do not constitute sufficient factual findings.” {underlining added}

Firstly, there is no reason to combine these three references. Nichols teaches a catheter device, for indeed, treating varicoceles. Col. 4, line 54. A first flexible elongate member is inside the catheter. Col. 4, line 59. A heating means is on the distal end of the first flexible elongate member. Col. 5, line 10. Also included is a second flexible elongate member that may be a guidewire. Col. 6, line 40. Del Diglio teaches the use of a standard needle for inserting an optical fiber into a vein, for example. Col. 5, lines 6 to 24. No further devices are included. Proebstle et al. demonstrate the use of an optical fiber connected to a 940 nm laser to destroy a blood filled vein by heating of the blood and thus damaging the wall.

Secondly, the applicant contends that this does not constitute sufficient factual findings.

The motivation provided by the Examiner is not found in the references but in a desire to combine these references to meet the elements in the present invention. MPEP 706(j), page 700-48, second column at top, states that the motivation for combining and success must be both found in the references, not in applicant's disclosure. {underlining added}

In light of these preliminary remarks, the applicant further states as to the rejections made in the last office action:

1. The Examiner has rejected Claims 1 to 5, and 7, 8, and 12 under 35 U.S.C. 103(a) as being unpatentable over Nichols in combination with Del Giglio and Proebstle et al. for the reasons noted on Page 2 of the Office Action.

A determination as to whether a valid rejection has been made begins with ascertaining that the PTO policy regarding the guidelines laid down by the Supreme Court in Graham v. John

Deere, 148 USPQ 459 (Sup. Ct. 1966) has been carried out. The PTO policy is simply that the patent Examiners carry the responsibility of making sure that the standard of patentability enunciated in this decision is applied in each case.

The proper test of obviousness is found in the four Graham inquiries: These inquires are determining the scope and content of the prior art, ascertaining the differences between the prior art and the claims at issue, resolving the level of ordinary skill in the pertinent art, and considering objective evidence present in the application indicating obviousness or non-obviousness. The issue to be resolved is whether these inquires have been correctly applied, considered and resolved.

It is further noted that the obviousness rejection should be directed at the claimed invention of the patent application in light of the teachings of the references, not that the claimed invention could be used on the cited references.

The Examiner states, "Nichols teaches a method of treating varicoceles by threading a catheter through the venous system and heating material in the vicinity of the end of the device, which can be done by laser radiation."

The applicant makes reference to Exhibit 1 being a University of Maryland Medical Center article relating to the treatment of varicoceles. As noted in the first paragraph, "Treatments include open surgical removal, laparoscopic removal, and catheter embolization." See also Exhibit 2 being the definition of a varicoceles. See also Exhibit 3 being a definition of embolization.

As noted by Nichols, col. 4, lines 32 to 39, the present invention is used to inactivate the organ" which would include a blood vessel, and further notes the "blockage of a blood vessel in a varicocele procedure." Col. 4, lines 54 to 55. No other description is included as to the varicoceles procedure used. As noted in col. 5, line 23 to 25, "laser energy" can be used to raise the temperature of the "heated surface" and/or the surrounding fluid. No example is given for the use of laser energy. Further, no example is given using an optical fiber. The heating source of Nichols is a resistance heating means that is positioned within an inflatable balloon. The examples given are treatment of a gallbladder and kidney.

It is thus asserted that Nichols does not teach a method of treating varicoceles.

The Examiner noted that "Del Giglio teach precise placement of an optical fiber ... beyond the tip of the introducer, and applying laser pulses."

Del Giglio teaches a method and device of applying laser energy to veins, in particular, for the purpose of closure. The laser energy is applied through an optical fiber inserted through a needle. A standard needle is attached to the hand piece and is then inserted through the skin and directly into the desired vascular structure. Col. 5, lines 25 to 30. Del Giglio discloses the treatment of wrinkles in Example 1, skin lifting or contracting in Example 2, superficial capillaries in Example 3, spider veins in Example 4, and varicose veins in Example 5. As noted in Example 4, in the treatment of spider nevus, the feeding vein is closed by several laser pulses. Col. 7, lines 58 to 62. As to the treatment of other body structures as noted in the present invention, no further details are provided. See Example 6. Further, Del Giglio does not disclose the preferred laser wavelengths in treating various structures.

Further, in the present invention, the critically of the use of the 980 nm wavelength is noted on page 6, second paragraph and included in Claim 1 as to its ability to close off veins. See also Example 1.

The article by Proebstle et al. shows that the “mechanism of EVLT action are(sic) still not completely understood.” Page 596, first paragraph. As noted in the article, vein perforation may result from the application of laser energy. As to the ability of steam generation by laser energy, it notes, page 599, last paragraph,

One may speculate if with such a continuous pullback technique, perforations of the vein wall during EVLT could be avoided. However, a too-slow pullback velocity would certainly lead to a completely perforating longitudinal cut in the vein wall. Further experiments are needed on this topic.

These experiments used 810, 940, and 980 nm laser energy.

Further, the applicant was well aware of the power of the 980 laser in cutting and ablation of veins and tissues which was clearly noted in this article and thus its use in sealing small veins in varices was problematical at the best.

It is therefore not obvious that the present invention would be unpatentable over the cited references since their teachings would indicate that the invention could not be used on delicate vein structures in varices.

2. The Examiner has rejected Claims 9 to 11 under 35 U.S.C. 103(a) as being unpatentable over Nichols in combination with Del Giglio and Proebstle et al. as applied to claims 1 to 5, 7 to 8, and 12 above, and further in combination with Farley et al. for the reasons noted on Page 2 of the Office Action.

The above traverse is incorporated by reference.

The Examiner states, "Farley et al teach a method of treating venous varicosities by threading a catheter through the venous system and confirming the position thereof with ultrasound, fluoroscopy, or angioscopy."

The use of the present invention in the areas noted is critical to the invention since these tissue areas are delicate tissues and are more likely to suffer damage from applications of the prior devices as noted above.

The use of the 980 nm laser has provided surprising results in these areas since prior uses were dedicated to the use of the 980 nm laser for cutting and coagulating tissues in surgery. The 980 nm laser is especially well absorbed in water as it is the second harmonic of the major OH stretching absorption peak at 2.94  $\mu$ m. The present invention is directed at the goal of collapsing or closing veins in the areas noted in the throat, varices or eye, not cutting the veins and/or merely coagulating them.

Farley et al. discloses a catheter for treating varicose veins with electrodes and an expandable section thereon. The complexity of the Farley et al. device is clearly shown in Figures 2 and 3 and discussed in related text as compared to the optical waveguide of the present invention. The device and method of treatment of Farley et al. is directed at venous insufficiency in the legs, ankles, and feet. See Col. 1, line 28, to Col. 2, line 43. Farley et al. note the treatment of vein valves. Col. 14, line 16. The application of the device of Farley et al. is discussed on Col. 15, lines 52 to 56, "The application of RF energy is terminated after there has been sufficient shrinkage of the vein to alleviate the dilation of the vein near the valve, so as to restore venous function or vulvar competency." Farley notes treatment of hemorrhoids for the purpose of shrinking the vein, Col. 17, line 55, to Col. 18, line 12. As stated, therein, "The electrode applies RF energy at a suitable frequency to minimize coagulation for a sufficient amount time to shrink, stiffen, and fixate the vein, yet maintain venous function ..." Treatment of other areas are noted as penile venous system for the purpose of again shrinking the veins, Col. 18., lines 13 to 33, and esophageal varices, Col. 18, lines 34 to 51. As noted therein, the treatment shrinks the veins.

“The amount of shrinkage of the vein can be limited to the diameter of the catheter itself, . . .” Col. 18, lines 27 to 29. Farley notes that other types of energy can be used in this treatment including lasers but fails to teach any details of such an application. Col. 18, lines 59 to 65. Claim 1 includes a step of “molding the hollow anatomical structure to a specific size using external compression.” Claim 5 notes the use of a laser, but fails to provide any further details of such treatment.

Farley et al. fail to teach a method of treating varices in the manner of the present invention, in the areas noted, and by means of selective radiation from a 980 nm laser resulting in actual closure, not just shrinkage as noted in the cited references.

As noted in relation to Claim 1, the above two references fail to teach the treatment of varices, which as discussed in the office interview, are in particularly more delicate areas of the body and thus require more refined, non-obvious treatment and devices. The beneficial use of laser radiation and laser radiation of 980 nm is not disclosed in the above two references. The present invention has found that the wavelength of 980 nm to be especially effective in the treatment of varices. See Page 6, lines 8 to 27.

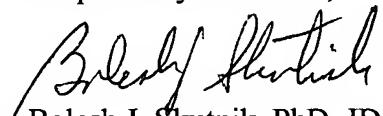
It is therefore asserted that these cited reference(s) clearly do not make obvious the invention for the reasons noted hereinabove. The features claimed in the reference do not function as in the present claims. Further this reference does not anticipate Claims 1, 2, 4, 5 and 7 to 12, since its disclosure is not in such full, clear, and exact terms as to enable any person skilled in the art to which the invention relates to practice it.

With these remarks it is believed that the requirements of 35 USC, 37 CFR and the MPEP have been answered and the disclosure and claims are now in condition for examination as one whole invention. Consideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Respectfully submitted,

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## Varicocele

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### Alternative Names:

Varicose veins - scrotum

### Treatment:

Varicoceles may be managed with a scrotal support. However, if pain continues, or if infertility or testicular atrophy results, further treatment may be needed. Treatments include open surgical removal, laparoscopic removal, and catheter embolization.

Both open and laparoscopic varicocelectomy (the surgical correction of a varicocele) are performed on an outpatient basis. The cut is usually made in the lower abdomen, although various techniques can be used. Ice packs should be kept to the area for the first 24 hours after surgery to reduce swelling.

Catheter ablation is also done as an outpatient procedure. A small puncture is made at the crease where the leg joins the body.

You will be advised to use ice and to wear a scrotal support for some time after surgery. Possible complications include hematoma (blood clot formation), infection, or injury to the scrotal tissue or structures. In addition, injury to the artery that supplies the testicle may occur.

### Expectations (prognosis):

A varicocele is usually harmless and often requires no treatment. If surgery is required because of infertility or testicular atrophy, the outlook is usually excellent.

EXHIBIT 1

**Calling your health care provider:**

Call for an appointment with your health care provider if you discover a testicle lump or need to treat a diagnosed varicocele.

**Varicocele****Male reproductive system**

- Review Date: 3/11/2005
- Reviewed By: David R. Knowles M.D., Scottsdale Urologic Surgeons, Scottsdale, AZ.  
Review provided by VeriMed Healthcare Network.



## Medical Dictionary

One entry found for **varicocele**.

Main Entry: **var-i-co-cele**

Pronunciation: 'var-i-kō-,sēl

Function: *noun*

: a varicose enlargement of the veins of the spermatic cord producing a soft compressible tumor mass in the scrotum

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### Pronunciation Key

|                          |                       |                      |
|--------------------------|-----------------------|----------------------|
| \a\ as a in about        | \g\ as g in go        | \r\ as r in red      |
| \'a\ə\ as u in about     | \h\ as h in hat       | \s\ as s in less     |
| \ə\ as e in kitten       | \i\ as i in hit       | \sh\ as sh in shy    |
| \ər\ as ur/er in further | \ī\ as ī in ice       | \t\ as t in tie      |
| \a\ as a in ash          | \j\ as j in job       | \th\ as th in thin   |
| \ā\ as a in ace          | \k\ as k in kin       | \th\ as th in the    |
| \ä\ as o in mop          | \k\ as ch in ich dien | \ü\ as oo in loot    |
| \au\ as ou in out        | \l\ as l in lily      | \ú\ as oo in foot    |
| \b\ as b in baby         | \m\ as m in murmur    | \v\ as v in vivid    |
| \ch\ as ch in chin       | \n\ as n in own       | \w\ as w in away     |
| \d\ as d in did          | \ŋ\ as ng in sing     | \y\ as y in yet      |
| \e\ as e in bet          | \ō\ as o in go        | \yü\ as you in youth |
| \'ē\ē\ as ea in easy     | \ō\ as aw in law      | \yü\ as u in curable |
| \ē\ as y in easy         | \oi\ as oy in boy     | \z\ as z in zone     |
| \f\ as f in fifty        | \p\ as p in pepper    | \zh\ as si in vision |

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## Medical Dictionary

One entry found for **embolization**.

Main Entry: **em·bo·li·za·tion**

Variant(s): or British **em·bo·li·sa·tion** /em-bo-lə-īzā-shən/

Function: *noun*

: the process by which or state in which a blood vessel or organ is obstructed by the lodgment of a material mass (as an embolus) <pulmonary embolization> <embolization of a thrombus>; also : an operation in which pellets are introduced into the circulatory system in order to induce embolization in specific abnormal blood vessels

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### Pronunciation Key

|                          |                       |                      |
|--------------------------|-----------------------|----------------------|
| \ə\ as a in about        | \g\ as g in go        | \r\ as r in red      |
| \'ə\ə\ as u in about     | \h\ as h in hat       | \s\ as s in less>    |
| \ə\ as e in kitten       | \i\ as i in hit       | \sh\ as sh in shy    |
| \ər\ as ur/er in further | \ī\ as ī in ice       | \t\ as t in tie      |
| \a\ as a in ash          | \j\ as ġ in job       | \th\ as th in thin   |
| \ā\ as a in ace          | \k\ as k in kin       | \th\ as th in the    |
| \ä\ as o in mop          | \k\ as ch in ich dien | \ü\ as oo in loot    |
| \au\ as ou in out        | \l\ as ī in lily      | \ú\ as oo in foot    |
| \b\ as in baby           | \m\ as m in murmur    | \v\ as v in vivid    |
| \ch\ as ch in chin       | \n\ as n in own       | \w\ as w in away     |
| \d\ as d in did          | \n\ as ng in sing     | \y\ as y in yet      |
| \e\ as e in bet          | \ō\ as o in go        | \yü\ as you in youth |
| \'ē\ē\ as ea in easy     | \ō\ as aw in law      | \yü\ as u in curable |
| \ē\ as y in easy         | \oi\ as oy in boy     | \z\ as z in zone     |
| \f\ as f in fifty        | \p\ as p in pepper    | \zh\ as sh in vision |

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**EXHIBIT 3**